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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/816,551	03/31/2004	Ronald W. Barrett	34545/US/4	9974

20686 7590 11/16/2010

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EXAMINER	
KIM, JENNIFER M	
ART UNIT	**PAPER NUMBER**
1628	

NOTIFICATION DATE	DELIVERY MODE
11/16/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

docketing-dv@dorsey.com
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Office Action Summary	Application No.	Applicant(s)	
	10/816,551	BARRETT ET AL.	
	Examiner	Art Unit	
	JENNIFER M. KIM	1628	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11/3/2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4-9,11-13,28,37,41 and 42* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 2, 4-9, 11-13, 28, 37, 41 and 42* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The response filed November 3, 2010 have been received and entered into the application.

Response to Arguments

Applicants' arguments filed November 3, 2010 have been fully considered but they are not persuasive. Applicants argue that those of skill in the art would not be motivated to treat hot flashes by administering an effective amount of 1-{[α-isobutanoyloxyethoxy)carbonyl]aminomethyl}-1-cyclohexane acetic acid in view of Guttuso because Guttuso describes numerous compounds for treating hot flashes, including, "without limitation, gabapentin and pregabalin". Therefore, Guttuso discloses a wide range of gabapentin and pregabalin prodrugs while Gallop is silent with respect to treating hot flashes. Accordingly, the skilled artisan would not select 1-{[α-isobutanoyloxyethoxy)carbonyl]aminomethyl}-1-cyclohexane acetic acid to treat hot flashes from among the myriad of possibilities disclosed in the combined Guttuso and Gallop references. This is not persuasive because Guttuso et al. clearly claimed a GABA analog of gabapentin or pregabalin is effective for the treatment of hot flashes (see claims). Guttuso et al. exemplified the actual treatment of hot flashes in a human by administration of representative GABA analog, i.e. gabapentin (see example 1). Therefore, there is a reasonable expectation of treating hot flashed in human by administration of a GABA analog including the instantly claimed compound, 1-{[α-

isobutanoyloxyethoxy)carbonyl]aminomethyl}-1-cyclohexane acetic acid, well taught by Gallop et al. as an analog of GABA among with gabapentin and pregabalin, which possesses a significant pharmaceutical use as being non-toxic. One would have been motivated to employ 1-{[α-isobutanoyloxyethoxy)carbonyl]aminomethyl}-1-cyclohexane acetic acid for the treatment of hot flashes in order to achieve not only the expected benefits of its GABA analog activity of treating hot flashes, but the additional significant non-toxic pharmaceutical advantages taught by Gallop et al. Thus, the claims fail to patentably distinguish over the state of the art as represented by the cited references.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 2, 4-9, 11-13, 28, 37, 41 and 42 are rejected under 35 U.S.C. 103(a) as being obvious over Guttuso (U.S.Patent No. 6,**3**10,098B1) in view of Gallop et al. (WO 02/0100347 A2), both of record.

Guttuso claims a method of treating hot flashes in a patient comprising providing a γ-aminobutyric acid (GABA) analog or salt thereof, wherein the analog includes gabapentin or pregabalin. Guttuso claims an effective amount of gabapentin analogs to be utilized in an amount of about 10 to 5000mg per day. These amounts encompass Applicants effective amounts set forth in claim 4. Guttuso claims female patients and male patients as subject populations to be treated with GABA analogs. Guttuso claims that female patient populations are postmenopausal. Guttuso claims that the cause of

the menopausal can be drug induced, surgically induced or naturally-occurring. Guttuso claims that the hot flashes experiences in male can be drug induced. Guttuso claims oral administration (see claims 1-14).

Guttuso does not expressly teach the compound 1-{[α-isobutanoyloxyethoxy)carbonyl]aminomethyl}-1-cyclohexane acetic acid as GABA analog.

Gallop et al. teach that the GABA analogs including gabapentin and pregabalin (abstract, page 1). Gallop et al. exemplify the instant compound, 1-{[α-isobutanoyloxyethoxy)carbonyl]aminomethyl}-1-cyclohexane acetic acid, as one of GABA analogs among with gabapentin and pregabalin effective for treating or preventing common disease and/or disorders treatable with GABA analogs (example 13, compound 77 on page 93). Gallop teaches that the analogs provide possess significant pharmaceutical advantages of particular use in medicine because it is typically labile *in vivo* and generate non-toxic metabolites. (page 4 line 22-page 5 line 20). Gallop et al. teach that the compound can be formulated for an oral delivery in the form of tablets or capsules and can be coated to provide sustained action over an extended period of time. (page 79, lines 16-25).

It would have been obvious to one of ordinary skill in the art to employ the compound, 1-{[α-isobutanoyloxyethoxy)carbonyl]aminomethyl}-1-cyclohexane acetic acid for the treatment of hot flushes in male or female subject population because GABA analogs including gabapentin and pregabalin are well known and effective for the treatment of hot flashes in male or female subject population as taught by Gallop et al.

and because the compound, 1-{[α-isobutanoyloxyethoxy)carbonyl]aminomethyl}-1-cyclohexane acetic acid is an analog of gabapentin and pregabalin which is useful for the common diseases that is treatable with GABA analogs. Moreover, the compound 1-{[α-isobutanoyloxyethoxy)carbonyl]aminomethyl}-1-cyclohexane acetic acid has benefit over the gabapentin and pregabalin that it generates non-toxic metabolites and labile in *vivo* as taught by Gallop et al. One would have been motivated to employ 1-{[α-isobutanoyloxyethoxy)carbonyl]aminomethyl}-1-cyclohexane acetic acid for the treatment of hot flashes in male or female in order to achieve an expected therapeutic benefit without generating toxic metabolites. There is a reasonable expectation of successfully treating hot flashes with the compound, 1-{[α-isobutanoyloxyethoxy)carbonyl]aminomethyl}-1-cyclohexane acetic acid because the compound is a GABA analog having chemical and structural moiety that is similar to gabapentin and pregabalin, therefore, the therapeutic utility of treating hot flashes would be retained. For these reasons the claimed subject matter is deemed to fail to patentably distinguish over the state of the art as represented by the cited references. The claims are therefore properly rejected under 35 U.S.C. 103.

None of the claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Communications

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JENNIFER M. KIM whose telephone number is (571)272-0628. The examiner can normally be reached on Monday through Friday 6:30 am to 3 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brandon Fetterolf can be reached on 571-272-2919. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/JENNIFER M KIM/
Primary Examiner, Art Unit 1628

Jmk
November 8, 2010